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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578

7590 08/13/2003

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Washington, DC 20004-1206

EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

33

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.

09/227,881

Applicant(s)

NGUYEN ET AL.

Examiner

J. Douglas Schultz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-81 and 91-126 is/are pending in the application.

4a) Of the above claim(s) 92, 93, 95, 98, 99, 101, 104, 104, 107, 110, 111, 113, 116, 117, 119, 122, 123, and 125

is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 94, 115, 118 and 120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01)

Office Action Summary

Part of Paper No. 33

Continuation of Disposition of Claims: Claims rejected are 79-81, 91, 96, 97, 100, 102, 35 U.S.C. § 103(a), 106, 108, 109, 112, 114, , 121, 124, and 126.

DETAILED ACTION

Status of Application/Amendment/Claims

1. Applicant's response filed May 27, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed February 25, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 92, 93, 95, 98, 99, 101, 104, 104, 107, 110, 111, 113, 116, 117, 119, 122, 123, and 125 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23, filed October 29, 2002.
4. Applicants arguments regarding restriction are moot since the requirement was made final in the previous Office action.

Response to Arguments

5. Claims 79-81, 91, 96, 97, 100, 102, 35 U.S.C. § 103(a), 106, 108, 109, 112, 114, , 121, 124, and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the

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written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the same reasons of record as set forth in the Official action mailed February 25, 2003.

Applicants have traversed the rejection above on the basis that applicants have provided sufficient description of the claimed genus of fragments 15 to 250 nucleotides long of SEQ ID NO: 3, wherein said fragments further comprise functional regulatory regions. Applicants maintain that they have “adequately met the written description requirement for genetic material ‘which requires a precise definition, such as by structure formula, chemical name, or physical properties’ by providing the express sequence of the claimed nucleic acids”, and further note that they have provided not only the sequence of SEQ ID NO: 3, but the chemical formula of the claimed molecules as well. Applicants assert that because the disclosure sets forth the sequence of SEQ ID NO: 3 and some fragments thereof, there is sufficient disclosure of the structure and formula of the claimed nucleotides necessary to possess the genus of fragments of SEQ ID NO: 3 described above. Applicants finally maintain that they need not identify and correlate functional regions of the claimed nucleic acids to meet the written description requirement where they have provided a precise definition, such as by structure and formula.

This argument is not considered convincing. Contrary to applicants arguments, The specification must provide some link between structure and function under the guidelines of 35 U.S.C. 101, which applicants have disclosed as fragments retaining translational control activity over the subject TIGR protein. Insofar as the connection between structure and function in

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supplying written description, M.P.E.P. § 2163 states that a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. It is maintained that applicants have not met this requirement for the claimed fragments.

Applicants are reminded at issue is whether adequate description exists for fragments that retain the correlated activity, not whether the whole of SEQ ID NO: 3 is adequately described. It is agreed that applicants have adequately described SEQ ID NO: 3. However, fragments of 15 to 250 nucleotides that are expected to retain some translational control over the expression of said protein have not been sufficiently described in the specification. In fact, such fragments have only been described in terms of their function (of modulating translation), along with a method of obtaining (from the 6000 nucleotide SEQ ID NO: 3). One of skill in the art would not have divined from the broad disclosure of a 6000 nucleotide sequence which actual fragments might retain such function. Although applicants have provided fragment sequences of SEQ ID NOS: 1-3 and 34 on page 28, applicant has not indicated any regulatory function for any such fragments. Thus, although it is possible to envision fragments of SEQ ID NO: 3 as alleged by applicants, it is not possible to envision such fragments having the broadly claimed function of "regulatory activity", and thus applicant is not considered to have disclosed sufficient identifying characteristics of structure and/or function. Nor have applicants provided any guidance which would direct one of skill in the art to those sequences within the 6000 bp SEQ ID NO: 3 which possess "regulatory function" as claimed other than the full SEQ ID NO: 3. Contrary to

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applicants' arguments, that identifying characteristics of a biomolecule may include a sequence or structure, applicants have not provided a sufficient and representative sample of structures that fully set forth the invention. Because the claimed fragments are described in the specification as those retaining translational control activity, and because applicants have not described a sufficient number of fragments that retain such a function, the rejection of record is maintained.

Allowable Subject Matter

6. Claims 94, 115, 118, and 120 are objected to as containing non-elected subject matter comprising SEQ ID NOS: 1, 2, and 34 that were restricted out as comprising distinct inventions, but not yet canceled by applicant. These claims would be allowable if rewritten to exclude subject matter drawn to the non-elected inventions, namely, SEQ ID NOS: 1, 2, and 34.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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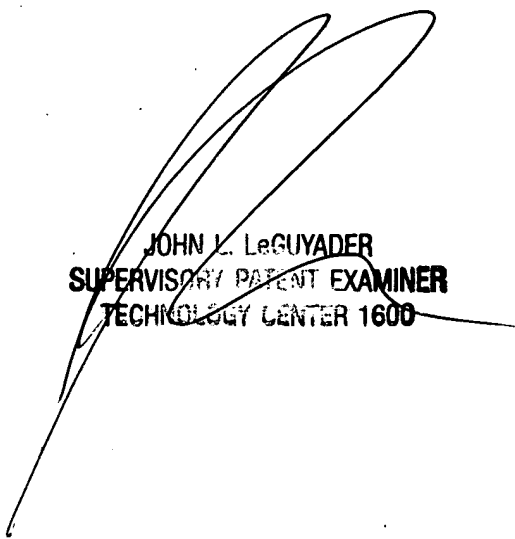
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
August 11, 2003



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600